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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/671,376

09/25/2003

Janina Baranowska-Kortylewicz

0685-UNMC.63184

1854

110

7590

09/14/2006

DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER

KRISHNAN, GANAPATHY

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/671,376	Applicant(s) BARANOWSKA-KORTYLEWICZ ET AL.	
	Examiner Ganapathy Krishnan	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed 6/29/2006 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

1. Claim 1 has been amended.
2. Remarks drawn to rejections under 35 USC 112, second paragraph and 103.

Claims 1-18 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been overcome by amendment to claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10059990 ('990 patent) newly cited in combination with Quivy et al (US 5,096,694) of record and Downer et al (Nuclear Medicine and Biology (2001, 28, 613-626) is being maintained for reasons of record.

Applicants argue that:

1. The '990 patent discloses uridine analogs as opposed to the deoxyuridine called for as a component of the claimed conjugates and does not disclose a conjugate with dihydrotestosterone (DHT). It also does not show how the radioactive metal nucleus is incorporated into the uridine phosphate structure to produce the radiolabelled derivatives. Even if it is bound somehow, it will not be recognized by the cell's DNA and hence will not be incorporated into the DNA. The applicants' deoxyuridine component of the conjugate is incorporated into the DNA of dividing cells.

2. Quivy et al does not teach a thymidine having a phospho group or DHT attached to it.

3. Downer does not teach the use of specific Auger emitting isotopes or conjugates comprising phospho thymidine or DHT as instantly claimed.

Hence, the combination of the references does not teach or suggest or provide the motivation to combine, according to the applicants.

This is not found to be persuasive.

The '990 patent teaches radioactively labeled uridine derivatives of structural formula I containing phospho groups (page 1 of Japanese version and English abstract), with radioactive metal nucleus species. These radiolabelled uridine derivatives of this invention are useful in imaging tumors because of their capability of accumulating in tumor cells (English abstract-

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Advantage, page 2). The sugar moiety taught in the '990 patent is structurally very close to the deoxysugar as instantly claimed and is also taught to be useful in tumor imaging. From this teaching one of ordinary skill in the art will recognize that a phospho substituted sugar moiety can be used as a component in tumor imaging.

Quivy et al teaches conjugates of thymidine labeled with Auger electron emitting radioisotopes like I-123 (col. 2, lines 16-64). These conjugates are used to treat a number of cancers with high concentrations of receptors for estrogens, progestagens and or androgens, which provide utility for the treatment of breast, uterus, ovary and prostate cancers (col. 4, lines 18-44). Quivy also teaches the use of labeled uracil attached to a deoxysugar as instantly claimed (col. 2, lines 45-64). Moreover, Quivy also teaches that the compounds of his invention are capable of binding to the DNA of target cells, i.e., cancer cells.

Downer et al teach that dihydrotestosterone was found to have a high uptake by prostate at 1 hour (page 619; section 3.3, lines bridging left and right columns). Cancers, especially prostate cancers express high amounts of androgen receptors. Hence androgens, like testosterone are useful in diagnosis and imaging of cancers and tumors (page 613, Introduction).

Quivy and the '990 patent may not teach conjugates as instantly claimed. But the fact that phospho substituted sugars that are structurally close to the one instantly claimed and radio-labeled dihydrotestosterone is found to have a high uptake by cancer cells as taught by Downer, suggests to one of ordinary skill in the art that phosphosugars can be used in imaging and dihydrotestosterone can be used as a carrier and a conjugate comprising both is also useful for imaging cancers and tumors.

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One of ordinary skill in the art will be motivated to make a phospho containing thymidine or uridine with an Auger electron emitting radiolabel and dihydrotestosterone and use the same in a method for treating and imaging tumors and cancers since such a combination has the advantage of high uptake due to the presence of the dihydrotestosterone moiety and the cancer cell destroying and imaging ability because of the presence of the Auger electron emitting radioisotope in a single compound.

Hence, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to make a radio labeled conjugate of thymidine and other bases containing phospho groups and dihydrotestosterone and use the same in a method treatment and imaging of tumors and cancers as instantly claimed with a reasonable expectation of success since the use of such is taught in the prior art.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Conclusion

Claims 1-18 are rejected

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

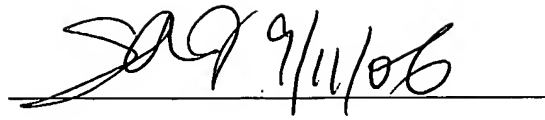
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'SAJ 9/11/06', is written over a horizontal line.

Shaojia A. Jiang
Supervisory Patent Examiner
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